

REMARKS

The specification was revised to remove a paragraph that was similar to the first paragraph.

Claims 1 to 37 appear in this application for the Examiner's review and consideration. The amendments are fully supported by the specification and claims as originally filed. Therefore, there is no issue of new matter.

Applicants acknowledge with appreciation the indication of allowable subject matter in claims 3, 4, 5, 6, 9, 12, 13, 14, 17, 18, 22, 23, 28, 30, 32, and 34, and submit that the other claims are allowable for the reasons set forth below.

Claims 1, 2, 7, 8, 10, 11, 15, 16, 19, 20, 21, and 24 were rejected under 35 U.S.C. §102(b), as allegedly being anticipated by U.S. Patent No. 5,880,283 to Masumoto et al. (Matsumoto) for the reasons set forth on pages 2 to 4 of the Office Action.

In response, Applicants submit that the presently claimed invention is directed to novel crystalline forms of gatifloxacin that are not explicitly or inherently disclosed in the prior art. In particular, the presently claimed invention is directed to:

A crystalline form of gatifloxacin, characterized by an x-ray reflection at about $17.2^\circ \pm 0.2^\circ 2\theta$, as recited in claim 1, that may be further characterized by an x-ray diffraction diagram substantially as shown in Figure 1, as recited in claim 2 (denoted form L in the present specification);

A crystalline form of gatifloxacin, characterized by x-ray reflections at about 8.8° , 14.1° , 17.6° , 18.2° , 22.0° , and $22.6^\circ \pm 0.2^\circ 2\theta$, as recited in claim 7, that may be further characterized by an x-ray diffraction diagram substantially as shown in Figure 2 (denoted form M in the present specification);

A crystalline form of gatifloxacin, characterized by x-ray reflections at about 11.1° , 11.7° , 12.5° and $23.0^\circ \pm 0.2^\circ \theta$, as recited in claim 10, that may be further characterized by an x-ray diffraction diagram substantially as shown in Figure 3, as recited in claim 11 (denoted form P in the present specification);

A crystalline form of gatifloxacin, characterized by x-ray reflections at about 6.8° , 7.1° , 11.1° , 15.5° , and $17.4^\circ \pm 0.2^\circ 2\theta$, as recited in claim 15, that may be further

characterized by an x-ray diffraction diagram essentially as shown in Figure 4, as recited in claim 16 (denoted form Q in the present specification);

A crystalline form of gatifloxacin, characterized by x-ray reflections at about 9.3°, 11.0°, and $21.2^\circ \pm 0.2^\circ 2\theta$, as recited in claim 19, that may be further characterized by at least one of x-ray reflections at about 12.0°, 14.5°, and 18.6°, $\pm 0.2^\circ 2\theta$, as recited in claim 20, and by an x-ray diffraction diagram substantially as shown in Figure 5, as recited in claim 21 (denoted form S in the present specification); and

A crystalline form of gatifloxacin, characterized by x-ray reflections at about 7.4°, 8.9°, 9.6°, 11.4°, 12.2°, 12.9°, 14.1°, 16.7°, 21.2°, 21.8°, 24.1°, and $26.0^\circ \pm 0.2^\circ 2\theta$, as recited in claim 24, that may be further characterized by an x-ray diffraction diagram essentially as shown in Figure 6, as recited in claim 25 (denoted form T1 in the present specification).

Matsumoto discloses gatifloxacin sesquihydrate, column 1, lines 9 to 12, and also discloses that gatifloxacin easily forms a hemihydrate when recrystallized from water containing organic solvent, column 1, lines 48 to 53. Applicants submit that those are the only forms of gatifloxacin explicitly or inherently disclosed by Matsumoto. As discussed in the present specification, at page 7, lines 15 and 16, the hemihydrate is crystalline form T2RP, disclosed in U.S. Patent No. 6,413,969. The hemihydrate, crystalline form T2RP, may be formed from form M, the crystalline form recited in claim 7, by prolonged (e.g. 2 months) storage at ambient temperature and pressure. Present specification, page 10, lines 6 and 7.

Matsumoto provides the x-ray diffraction pattern of the disclosed gatifloxacin sesquihydrate in Figure 5 and that of a comparative material in Figure 6. Copies of Matsumoto Figures 5 and 6, scaled to approximately match the scale of the x-ray diffraction patterns of Figures 1 to 6 submitted with the present application, are attached for the convenience of the Examiner. An Examination of the x-ray diffraction patterns of Figures 5 and 6 quickly demonstrates that the forms of gatifloxacin disclosed by Matsumoto are not those presently claimed. Neither of the x-ray diffraction patterns disclosed by Matsumoto is characterized by all the x-ray reflections that correspond to those recited in any of the present claims for the presently claimed crystalline forms of gatifloxacin.

That is, the forms of gatifloxacin disclosed by Matsumoto are not characterized by the x-ray diffraction patterns substantially as shown in any of Figures 1 to 6 of the present application, and the forms of gatifloxacin disclosed by Matsumoto are not characterized by an x-ray reflection at about $17.2^\circ \pm 0.2^\circ 2\theta$, as recited in claim 1, x-ray reflections at about 8.8°,

14.1°, 17.6°, 18.2°, 22.0°, and 22.6° ± 0.2° 2θ, as recited in claim 7, x-ray reflections at about 11.1°, 11.7°, 12.5° and 23.0° ± 0.2° θ, as recited in claim 10, x-ray reflections at about 6.8°, 7.1°, 11.1°, 15.5°, and 17.4° ± 0.2° 2θ, as recited in claim 15, x-ray reflections at about 12.0°, 14.5°, and 18.6°, ± 0.2° 2θ, as recited in claim 20, or x-ray reflections at about 7.4°, 8.9°, 9.6°, 11.4°, 12.2°, 12.9°, 14.1°, 16.7°, 21.2°, 21.8°, 24.1°, and 26.0° ± 0.2° 2θ, as recited in claim 24.

Moreover, as Matsumoto discloses only two specific crystalline forms of gatifloxacin, the sesquihydrate and the hemihydrate, methods of preparing those two specific crystalline forms of gatifloxacin, and only two x-ray diffraction patterns that do not correspond to any of the presently claimed crystalline forms of gatifloxacin, the presently claimed crystalline forms of gatifloxacin are not inherent to the disclosure of Matsumoto. Therefore, Matsumoto does not disclose the presently claimed crystalline forms of gatifloxacin explicitly or inherently.

Therefore, as Matsumoto does not explicitly or inherently disclose the presently claimed crystalline forms of gatifloxacin, the present claims are not anticipated by that reference. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 1, 2, 7, 8, 10, 11, 15, 16, 19, 20, 21, and 24 under 35 U.S.C. §102(b) over Masumoto.

Claims 2, 8, 9, 11, 16, 21, 25, 26, 27, 29, 31, 33, 35, 36, and 37 were rejected under 35 U.S.C. 112, second paragraph, for the reasons set forth on pages 4 and 5 of the Office Action, and claims 18, 28, 30, 32, and 34 were rejected under 35 U.S.C. 112, second paragraph, for the reasons set forth on page 4 of the Office Action. In particular, the Office Action states that reference to figures outside of the claim set are not permitted, rendering these claims indefinite.

In response, Applicants submit that M.P.E.P. § 2173.05(s) states:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table “is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant’s convenience.” *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Therefore, reference in a claim to a figure of and by itself does not render the claim indefinite.

In the present case, one of ordinary skill in the art would understand that the presently claimed crystalline forms of gatifloxacin, as recited in claims 2, 8, 11, 16, 21, and 25, have x-ray diffraction patterns that are substantially the same as those shown in Figures 1 to 6, respectively, and, thus, each such x-ray diffraction pattern referenced in a claim is a particular characteristic of the claimed crystalline form of gatifloxacin recited in that claim. As there is no practical way to characterize each crystalline form of gatifloxacin by its complete x-ray diffraction pattern in words, and it is clearly more concise to incorporate the figures by reference than by duplicating those figures into the claims, reference in the claims to those figures is permissible, and does not render the claims indefinite.

Therefore, the claims particularly point out and distinctly claim the subject matter Applicants regard as the invention, and the claims are not indefinite. Accordingly, it is respectfully requested that the Examiner withdraw the rejections of claims 2, 8, 9, 11, 16, 21, 25, 26, 27, 29, 31, 33, 35, 36, and 37 and claims 18, 28, 30, 32, and 34 under 35 U.S.C. §112, second paragraph.

Claims 9 and 18 were objected to for depending from a higher numbered claim. In response, applicants have amended those claims to change the dependencies, such that claim 9 depends from claim 8, and claim 18 depends from claim 17. Accordingly, it is respectfully requested that the Examiner withdraw the objection to claims 9 and 18.

Claims 3, 4, 5, 6, 9, 12, 13, 14, 17, 18, 22, 23, 28, 30, 32, and 34 were objected to for depending on a rejected base claim. In response, Applicants submit that, for the reasons set forth above, the base claims are in conditions for allowance. Accordingly, it is respectfully requested that the Examiner withdraw the objection to claims 3, 4, 5, 6, 9, 12, 13, 14, 17, 18, 22, 23, 28, 30, 32, and 34.

Applicants thus submit that the entire application is now in condition for allowance, an early notice of which would be appreciated. Should the Examiner not agree with Applicants' position, a personal or telephonic interview is respectfully requested to discuss

any remaining issues prior to the issuance of a further Office Action, and to expedite the allowance of the application.

Respectfully submitted,

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